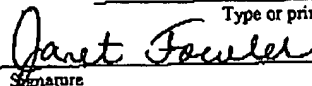


JUN 13 2005

CERTIFICATION OF FACSIMILE TRANSMISSION	
I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below to 703-872-9306	
Janet Fowler	
Type or print name of person signing certification	
	June 13, 2005
Signature	Date

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: James Arthur Hoffmann)	
Serial No.	: 10/072,540)	
Filed	: February 8, 2002)	Group Art Unit:
For	: GLP-1 Formulations)	1614
Docket No.	: X-11368A)	Examiner:
)	Delacroix-Muirheid

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On 6 June 2005, Applicant filed a Request for Continued Examination under 37 C.F.R. § 1.114 of U.S. Serial No. 10/072,540. In response to the Final Rejection (Paper No. 122804) dated January 11, 2005, Applicant also submitted a response, an amended IDS form 1449, and a Declaration under 37 C.F.R. § 1.131 from the inventor and Applicant, James Arthur Hoffman. In addition, a petition for a two-month extension of time under 37 C.F.R. § 1.136 was also included in the mailing.

It has come to my attention that Exhibit A (that was to accompany the Declaration of Applicant James Hoffmann) was inadvertently omitted from this case.

Serial No. 10/072,540

Applicant respectfully requests that the Examiner enter the Exhibit A into the 6 June 2005 Declaration. If for any reason, the Examiner feels a telephone conversation would be helpful, the Examiner is urged to call me.

Respectfully submitted,



Gregory A. Cox
Attorney for Applicant
Registration No. 47,504
Phone: 317-276-0280

Eli Lilly and Company
Patent Division/GAC
Lilly Corporate Center
Indianapolis, Indiana 46285

June 13, 2005

Project No. E2BBook No. LIA

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VE-62-1 Formulations + Additives

Procedure: Find other excipients that allow VE-62-1 (2.57) to stay clear in formulations with 2.15 mg/ml m-cresol at pH 6.75 at RT and 4°C.

Procedure: VE-62-1 (2.57) was prepared at (mg/ml) 2.57 mg/ml (by weight) in 100mM sodium phosphate Tris buffer - 16 mg/ml m-cresol (pH 6.75) adjusted to pH 6.00 with 2N HCl. m-cresol used at 100 mg/ml is ethanol.

For each sample below to 500 µl of VE-62-1 solution was added the minimum before 30-60 at RT. 15 µl of the m-cresol solution was added. Mix and store at RT 2-4 hr.

ESA-71

Sample

Additive

w/ m-cresol
Stay Clear
at RT?

V	10 µl Tween 40	OK	Yes
W	10 µl Tween 80	OK	Yes To Page No. 7
Witnessed by me,		Date	Invented by James A. Hoffmann
		Date	3/6/97
		Recorded by	A. Hoffman

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Project No. 622Book No. 178Title US-622-1 / m-cresol Emulsions + Additives

From Page No. _____

Procedure: cont.

All 6 samples that remained clear at RT during the day (2-4 hr) were covered with parafilm and placed in the refrigerator (4°C).

Two more samples were made up later in the day:

Sample	Additive	OK	Very important Stay clear at RT
X	1ml Tween 40	OK	Almost
Y	1ml Tween 80	OK	No

Sample Y had a lot of biomass and precipitates came right away, while sample X had only a trace of biomass after 45' at RT.

After overnight at 4°C, all solutions that had remained clear at RT were checked. None was totally clear, although sample W was almost clear.

Results: several additives in the US-622-1 / m-cresol / glycerin emulsion help maintain clarity at RT.

and 2% Tween. At these levels, though, none of the additives was able to keep the emulsion clear at 4°C overnight in the refrigerator.

On rewarming to RT, all 6 samples reclarified pretty readily.

The aggregation phenomenon at 4°C leads to biomass thus appears to be reversible.

Conclusions: several additives

(2% Tween 40 or 80) improve solubility of US-622-1 in emulsions with m-cresol and glycerin at RT, especially at ambient temperature.

Witnessed & Understood by me, _____

Date _____

Invented by Joanna A. Hoffmann

Date _____

Recorded by _____

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